

REMARKS

Applicant thanks the Examiner for consideration of the subject patent application. In the office action mailed October 23, 2005, the Examiner acknowledged the provisional election without traverse of Group 1, claims 1-62 and the species sucrose, which was made by Applicant in the restriction requirement response filed on October 11, 2005. Applicant affirms the election of the group and the species as disclosed above. Claims 1-35 have been canceled and new claims 64-67 have been added.

Claims 1-62 were rejected as allegedly being obvious over U.S. Patent Nos. 6,103,756 to Gorsek (hereinafter "Gorsek"), or 5,785,977 to Breitbarth (hereinafter "Breitbarth"), taken with U.S. Patent Nos. 3,615,687 to Mochizuki (hereinafter "Mochizuki"), 6,534,063 to Fallon (hereinafter "Fallon"), 5,902,617 to Pabst (hereinafter "Pabst") or 4,378,434 to Prentice et al. (hereinafter "Prentice"), Chinese Publication no. 1096457 to Liang et al. (hereinafter "Liang"), U.S. Patent Nos. 5,597,585 to Williams et al. (hereinafter "Williams") or 6,020,351 to Pero (hereinafter "Pero"), 6,447,809 to Krumhar et al. (hereinafter "Krumhar"), 6,461,607 to Farmer (hereinafter "Farmer") or 5,759,520 to Sachetto (hereinafter "Sachetto"), 6,042,823 to Kimura et al. (hereinafter "Kimura"), and 6,451,341 to Slaga et al. (hereinafter "Slaga"). Applicant respectfully submits that the rejected claims are patentable over the cited reference for the reasons set forth herein, and that the rejection should be withdrawn.

Before discussing the rejection, it is thought proper to briefly state what is required to sustain such a rejection. The issue under § 103 is whether the PTO has stated a case of *prima facie* obviousness. "The PTO has the burden under § 103 to establish a *prima facie* case of obviousness." *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). To satisfy this burden, the PTO must meet the criteria set out in M.P.E.P. § 706.02(j):

... three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Moreover, the obviousness analysis must comply with the statutory scheme as explained

by the Supreme Court in Graham v. John Deere Co., 383 U.S. 1, 17 (1966), namely, consideration must be given to: (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention, (3) the level of ordinary skill in the pertinent art, and (4) additional evidence, which may serve as indicia of non-obviousness.

With the above background in mind, Applicant contends that the burden of making a *prima facie* case of obviousness has not been met, and that the claims of the present invention are distinct from the references asserted.

Applicant's Invention:

As recited in Claim 36, the present invention includes a nutrient absorption increasing composition that includes:

A nutrient absorption increasing composition comprising:

- a) an amount of *Aspergillus* derived protease having a protein hydrolyzing activity of from about 1,000 HUT, to about 60,000 HUT, and a calcium compound cofactor which provides calcium in a ratio of at least about 1 mg of calcium for every 1200 HUT of protease activity;
- b) an amount of an *Aspergillus* derived lipase having a lipid hydrolyzing activity of from about 10 LU to about 800 LU, and a zinc compound cofactor which provides zinc in a ratio of at least about 1 mg of zinc for every 800 LU of lipase activity;
- c) an amount of an *Aspergillus* derived cellulase having a cellulose hydrolyzing activity of from about 3 CU to about 400 CU, and a manganese compound cofactor which provides manganese in a ratio of at least about 1 mg of manganese for every 400 CU of cellulase activity; and
- d) an amount of an *Aspergillus* derived amylase having a starch hydrolyzing activity of from about 1,000 DU to about 20,000 DU, and a magnesium compound cofactor which provides magnesium in a ratio of at least about 1 mg of magnesium for every 20,000 DU of amylase activity.

As such, the composition can be administered to a subject in order to increase subject's ability to absorb specific types of nutrients through the hydrolysis activity induced by each pertinent enzyme. Additionally, it is noteworthy that each enzyme is accompanied by a specific catalysis enhancing mineral cofactor, which increases the ability of the enzymes to catalyze the in

vivo hydrolysis of each designated nutrient.

The Applicant wishes to note that an important element of the present invention, and in particular of claim 36, is that the enzymes are not merely combined together into the nutrient absorption increasing composition, accompanying the enzymes are enzyme cofactors specific to each of the *Aspergillus* enzymes at prescribed ratios. The association of the required enzyme at the minimum ratios provides for greatly enhanced activity of the enzyme, a key benefit of the present invention.

Gorsek:

This reference teaches compositions for treating or preventing ocular degeneration. In particular, a composition containing a variety of vitamins, minerals and nutrients is taught. The composition can also include "plant enzymes" such as amylase, cellulase, protease, lipase, and lactase. No specific sources for the enzymes are taught or suggested, and *Aspergillus* is not mentioned. Moreover, while a calcium and zinc are taught for optional inclusion, and magnesium is taught to be essential, there is no teaching or suggestion that such ingredients are included or necessary for the purposes of improving the catalyzing ability of the "plant enzymes". Further, there is no teaching or suggestion that each mineral acts as a specific cofactor for a certain enzyme. In fact, no specific purpose for either the minerals or the enzymes is taught or suggested.

Breitbarth:

This reference teaches non-metallic microparticulate carrier materials for pharmaceutical and cosmetic agents. A fairly large number of active agents are taught as acceptable for use with the microparticle carrier including, calcium, magnesium, zinc, amylase, protease, lipase, and cellulase. However, no specific source for any of the enumerated enzymes is taught, and no mention of *Aspergillus* is made. Further, there is no teaching that all of these recited ingredients must be present in a single formulation. Additionally, no teaching or suggestion of the purpose for either the minerals or the enzymes is made, and there is no teaching that any specific mineral acts as a cofactor for any given enzyme.

Mochizuki:

This reference teaches an enzyme composition that is used for candying fruit. The enzymatic composition is produced by the cultivation of *Aspergillus niger*. Specifically, the use of the enzymatic composition is taught to shorten the time required for candying by increasing the rate at which sugar impregnates the fruit. See, col. 3, ln. 6-11. The enzymatic composition includes many kinds of enzymes including pectinase, protease, cellulase, hemicellulase, peptidase, glucanase, RNA depolymerase, sucrase, maltase, lactase, xylanase, inulanase, dextranase, mannose, alpha-amylase, beta-amylase, lipase, and cellobiase. See, col. 56-61. The *Aspergillus niger* is taught to be incubated on either solid or liquid mediums. Such mediums are taught to contain carbon and nitrogen sources which are assimilable by the *Aspergillus*. Further, various mineral salts such as calcium salts, magnesium salts, potassium salts, sodium salts, zinc salts, copper salts, iron salts, and vitamins may be added to the culture medium as accessory nutrients to help culturing. See, col. 2, ln. 1-18.

Nothing in the reference teaches or suggests that the enzymes in the composition are used to catalyze hydrolysis of specific compounds. Rather, the purpose of the enzyme composition is increase the rate at which sugar impregnates fruit and thereby shorten the time required for candying. Further, nothing in the reference teaches or suggests that any specific minerals are used as cofactors for the purpose of increasing the catalyzing abilities of certain enzymes. Rather, they are taught for inclusion in the culture medium as accessory nutrients to aid in culturing. Moreover, no specific match is taught between minerals and corresponding enzymes.

Fallon:

This reference teaches a method of analyzing fecal chymotrypsin levels as a measure of success in using secretin, other neuropeptides, peptides and/or digestive enzymes treat or ameliorate Pervasive Development Disorders (PDD). The digestive enzymes taught include amylases, proteases, lipases, sucrase, maltase, and other digestive enzymes. Nothing in the reference teaches or suggests a specific source for such enzymes. Further, no mention of any minerals is made in the reference. Moreover, nothing in the reference teaches or suggests that specific mineral cofactors are matched to particular enzymes for the purpose of increasing the hydrolysis catalyzing activity of each enzyme.

Pabst:

This reference teaches an enzyme supplemented baby formula. The enzymes are added to the formula for the purpose of imitating the digestive enzymes present in breast milk. Examples of the enzymes include proteases, and carbohydrate degrading enzymes such as alpha-amylase, lactase, fructose, sucrase, and lipase. Specific sources are taught for certain enzymes. For example, Papain is taught as the source for protease, and *Aspergillus niger* is taught as a source for various carbohydrate degrading enzymes, such as lactase, fructose, and sucrase, and a marketed formulation of such is exemplified by the Beano TM extract sold by the Lactaid company. The infant formula composition may contain a number of additional additives, and is provided with an enteric coating in order to allow the enzymes to reach the intestine without being destroyed by the low pH of the stomach. However, the composition does not include any specific minerals, and the reference provides no teaching of such. Moreover, nothing in the reference teaches or suggests that specific minerals are used as cofactors for the purpose of increasing the hydrolyzing catalysis activity of specific enzymes.

Prentice:

This reference teaches a device and process for making cultures and withdrawing metabolites produced by the cultures. Most prominently exemplified is a culturing process for making beer. While the reference teaches various carbohydrate degrading enzymes, no source is taught for such enzymes, and no other types of enzymes are mentioned. Further, the reference does not teach or suggest the inclusion of any minerals, and does not teach or suggest the use of enzyme specific minerals as cofactors for the purpose of increasing the catalytic abilities of hydrolyzing enzymes.

Liang:

This abstract teaches a tablet for preventing babies from regurgitating milk that is a pure biological composition containing a combination of enzymes, vitamins, and minerals. Proteolytic enzymes are recited generally, as well as calcium and zinc. Nothing in the abstract teaches or suggests any source for any specific enzymes. No mention of *Aspergillus* is made.

Further, while zinc and calcium are included in the formulation, there is no teaching or suggestion that such minerals are included for the purpose of acting as cofactors for increasing the catalyzing activity of specific enzymes.

Williams:

This reference teaches vitamin and mineral compositions. The compositions may take the form of a dry powder that may be dispensed into water as a beverage. While certain minerals are included in the composition, no enzymes are taught for inclusion in the composition. In fact, no enzymes are mentioned at all by the reference. Furthermore, nothing in the reference teaches or suggests the use of specific minerals as cofactors for increasing the catalytic abilities of specific hydrolyzing enzymes to which they are matched.

Pero:

This reference teaches a combination of carotinoids, nicotinamide, and zinc for reducing cellular DNA damage. Zinc, calcium, and magnesium are specifically taught for inclusion. Further, zinc is taught to be a cofactor for several specific enzymes used in DNA replication. However, no mention is made of hydrolyzing enzymes. Moreover, the reference contains no teaching or suggestion of using specific mineral cofactors for the purpose of increasing the catalytic activity of specific hydrolyzing enzymes to which the mineral cofactors are matched.

Krumhar:

This reference teaches a dietary supplement for benefiting human bone health which includes a calcium source, a Vitamin D source, and an osteoblast stimulant. Zinc and manganese are taught for inclusion in a long list of other minerals. However, the reference fails to mention hydrolyzing enzymes, and does not teach or suggest the use of the disclosed minerals as specific cofactors for the purpose of enhancing the catalytic activity of specific hydrolyzing enzymes.

Farmer:

This reference teaches bacteria resistant probiotic organisms for treatment and prevention of parasites. Aspergillus is mentioned as a mycotic organism against which, the composition is

effective. Enzymes and minerals are generally mentioned as optional ingredients for the composition. However, no specific enzymes are mentioned, let alone hydrolyzing enzymes. Moreover, nothing in the reference teaches or suggests the use of specific minerals as cofactors for the purpose of improving the catalytic activity of specific hydrolyzing enzymes.

Kimura:

This reference teaches enzyme compositions for forming oligosaccharides in vivo. The enzymes taught for inclusion in the composition include glucosyltransferase, levansucrase, and amylase. *Aspergillus* is taught as source for transferase and amylase. However, no mention is made of other enzymes, and no mention is made of any minerals for inclusion in the composition. Additionally, the reference contains no teaching or suggestion of using specific minerals as cofactors for the purpose of improving or enhancing the catalytic abilities of specific hydrolyzing enzymes matched to the minerals.

Sachetto:

This reference teaches an aerosol with delayed foaming action for administration of substances into the rectal and vaginal cavities. Enzymes generally and magnesium citrate are taught for inclusion in the aerosol composition. However, the reference does not mention any enzymes in specific, and does not recite any hydrolyzing enzymes. Further, the reference does not contain any teaching or suggestion of using any specific minerals as cofactors for the purposes of improving the catalysis properties of given hydrolyzing enzymes.

Slaga:

This reference teaches vitamin and mineral supplements with potential anti-cancer effects. Enzymes of superoxide dismutase and catalase are included. *Aspergillus* is taught as a possible source for such enzymes. Various minerals including zinc, magnesium, and calcium can also be included in the formulation. However, there is no mention of any specific hydrolyzing enzymes, nor of the use of any specific minerals as catalysis enhancing cofactors for use in combination therewith.

Non-obviousness Arguments:

While the issue of obviousness turns on a determination of what would or would not be obvious to one having ordinary skill in the art, it nevertheless is a question of law and not of fact. *In re Vaeck*, 20 USPQ2d, 1438, 1442 (Fed. Cir. 1991); *In re Woodruff*, 16 USPQ2d 1934, 1935 (Fed. Cir. 1990). The burden is on the Examiner to establish a case of *prima facie* obviousness. When attempting to do this by combining references, the Examiner must show that each and every element of the present invention is taught or suggested by the combination. One case that supports and expounds on this element is *In re Ehrreich et al.*, 200 USPQ 504, 509-511 (CCPA 1979). Specifically, in finding that the "subject matter as a whole" would not have been obvious in *Ehrreich* the court concluded:

"Thus, we are directed to no combination of prior art references which would have rendered the claimed subject matter as a whole obvious to one of ordinary skill in the art at the time the invention was made. The PTO has not shown the existence of all the claimed limitations in the prior art or any suggestion leading to their combination in the manner claimed by applicants."
(underlining added)

Applicant contends that the combination of the above-recited references fails to teach each and every element of the claimed invention. As shown by Claim 36 recited above, the present invention includes a specific combination of *Aspergillus* derived enzymes, each accompanied by a specific mineral cofactor at a required minimum ratio which enhances the catalysis activity of the enzyme. Nothing in any of the references, either individually or collectively, teaches or suggests the use of minerals as cofactors for improving enzyme catalysis activity of the claimed *Aspergillus* enzymes. More specifically, nothing in the combination of references links any of the specific mineral cofactors to any of the specific *Aspergillus* derived enzymes for enhancing the catalysis abilities thereof.

In addition to the failing to teach the specific combinations of cofactors and enzymes, the cited references individually and collectively do not teach the amounts of the mineral cofactors present. Presently pending claim 36 states that each of the mineral cofactors is present at a minimum ratio with respect to the enzymes activity. Further, dependent claims 53-56 also teach specific cofactor to enzyme activity ratio ranges. Nothing in any of the cited references teaches or discloses the specific correlation of a particular cofactor with a particular enzyme nor do they

disclose the ratios of cofactor to enzyme activity as disclosed above. As a result, the combination of references fails to teach each and every element of the claimed invention, and does not support a *prima facie* case of obviousness. Therefore, Applicant contends that the rejection is improper and respectfully requests that the rejection be withdrawn.

Additionally, it is well known that in order to reject claims using a combination of references, the Examiner must show or establish that the references themselves contain a sufficient motivation or suggestion to be combined, or that such suggestion would be found within the knowledge of one ordinarily skilled in the art. *In re Dillon*, 16 USPQ 2d 1897, 1901 (Fed. Cir. 1990). Moreover, as stated in *In re Jones*, 21 USPQ 2d 1941, 1943-44 (Fed Cir. 1992):

"....Before the PTO may combine the disclosure of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art..... Conspicuously missing from this record is any *evidence*, other than the PTO's speculation (if it be called evidence) that one of ordinary skill in the.. art would have been motivated to make the modifications of the prior art necessary to arrive at the claimed (invention)."

Applicant contends that the Examiner has failed to show sufficient motivation or suggestion to combine the inordinate number of references cited. Applicant notes that in the present office action, the Examiner relies on the well-known principle that it is *prima facie* obvious to combine elements, each of which is separately taught for the same purpose, in order to form a third composition. However, no such common purpose is taught by the references for each of the elements recited by the presently claimed invention. In fact, as can be seen from the reference summaries above, when viewed as a whole, very few of the references have any common purpose at all, and none teaches or suggests any minerals for the purpose of acting as cofactors to enhance the catalytic abilities of *Aspergillus* derived hydrolyzing enzymes. Moreover, nothing in any of the references teaches or suggests specific minerals for the purpose of being used as cofactors to improve the catalytic action of specific *Aspergillus* derived hydrolyzing enzymes to which the minerals are matched. As such, Applicant respectfully submits that no *prima facie* case of obviousness has been established, and that the combination of references is improper. Therefore, Applicant respectfully requests that the rejection be

withdrawn.

Further, Applicant contends that the present combination of references has been assembled impermissibly based on hindsight reconstruction of Applicant's invention. Applicant simply cannot see any motivation to combine the inordinate number of reference outside of motivation obtained only after a review of Applicant's disclosure, and further Applicant submits that the inordinate number of references required to make the rejection acts as evidence in this regard. As can be seen from the reference summaries recited above, when viewed as a whole, each reference has very little in common with the other references, and in fact, sufficient differences exist in many cases that may qualify certain references as not analogous to the others. For example, Gorsek teaches a composition for improving ocular health, while Mochizuki teaches a composition for candying fruit. Further, Fallon teaches a method for determining whether various enzymes have a positive effect in treating PDD's and Prentice teaches compositions and methods for making beer. Additional differences are highlighted by a comparison of Pero which teaches a composition for reducing damage to cellular DNA, and Sachetto which teaches an aerosol composition for delivery into the rectal or vaginal cavities. Moreover, as recited above, no common purpose has been established for each of the elements contained in the present claims by the combination of references, and the purpose for the minerals required by the present claims of acting as cofactors for enhancing the catalytic abilities of specific enzymes is not found in the combination of references. Accordingly, Applicant submits that the rejection is impermissibly based on hindsight reconstruction of the references in view of Applicant's disclosure, and requests that it be withdrawn.

CONCLUSION

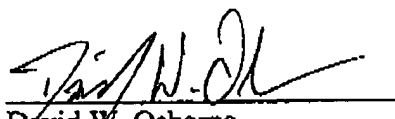
Based on the foregoing, Applicant contends that the burden of establishing a *prima facie* case of obviousness of presently pending Claims 36-67 has not been met. Rather, the references fail to teach or suggest each and every element of independent Claim 36, and also fail to provide sufficient motivation or suggestion to compel the combination thereof. As such, Applicant contends that the combination of the inordinately high number of references is impermissibly based on hindsight reconstruction in view of Applicant's disclosure, and that such an inordinate number of references combined supports such a position. As such, Applicant respectfully submits that presently pending Claims 36-67 present patentable subject matter, and allowance thereof is respectfully requested.

If any impediment remains after consideration of the above-recited remarks, which could be removed during a telephone interview, the Examiner is invited to telephone Mr. David Osborne of this office, or in his absence, the undersigned attorney, at (801) 566-6633 so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue fee or credit any overpayment to Deposit Account No. 20-0100.

DATED this 19th day of April, 2006.

Respectfully submitted,



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